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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,150	07/18/2003	Anne Marie Heegaard	59573(46865)	5193

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EXAMINER

DUNSTON, JENNIFER ANN

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1636

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12/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/623,150	Applicant(s) HEEGAARD ET AL.	
	Examiner Jennifer Dunston, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,18,21,22 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9,18,21,22 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of an amendment, filed 9/11/2008, in which claim 11 and 27 were canceled, and claims 9 and 18 were amended. Currently, claims 9, 18, 21, 22 and 28 are pending and under consideration.

Any rejection of record in the previous office actions not addressed herein is withdrawn. New grounds of rejection are presented herein that were not necessitated by applicant's amendment of the claims since the office action mailed 6/11/2008. Therefore, this action is not final.

Information Disclosure Statement

Receipt of an information disclosure statement, filed on 6/23/2008, is acknowledged. The signed and initialed PTO 1449 has been mailed with this action.

Claim Objections

Claim 9 is objected to because of the following informalities:

1. In line 3, an "s" should be added to the word "channel" to improve the grammar of the claim.
2. In line 6, a hyphen should be inserted into the word "CIC7" to be consistent with the nomenclature used in the claims.
3. In line 8, the word phrase "Paget's disease of the bone" should be changed to "Paget's disease of bone" to be consistent with the terminology used in the specification (e.g., page 4, line 13).

Claim 28 depends from claim 9 and is objected to for the same reasons applied to claim 9. Appropriate correction is required.

Claim 28 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 28 requires the screening method to identify compounds having potential activity in treating an osteoclast related bone disease; however, claim 28 depends from claim 9, which recites, "wherein the screening method identified compounds having potential activity in treating osteoporosis, osteolytic cancer invasion, or Paget's disease of the bone." Thus, the diseases recited in claim 9 are narrower in scope than the disease recited in claim 28. Accordingly, claim 28 attempts to broaden the scope of claim 9.

Claim 18 is objected to because of the following informalities: at lines 4-5, the claim refers to "the chloride channel ClC-7". Since this is the first mention of channel ClC-7 in the claim, the word "the" should be deleted. Claims 21 and 22 depend from claim 18 and thus are objected to for the same reasons applied to claim 18. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9, 18, 21, 22 and 28 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59 and 60 of copending Application No. 10/622,377 (hereinafter the '377 application). This rejection was made in the Office action mailed 6/11/2008 and has been rewritten to address the amendments to the claims in the reply filed 9/11/2008.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 9, 18, 21, 22 and 28 are generic to all that is recited in claim 59 of the '377 application. That is, claim 59 of the '377 application falls entirely with the scope of claims 9, 18, 21, 22 and 28 of the instant application or, in other words, instant claims 9, 18, 21, 22 and 28 are anticipated by claim 59 of the '377 application. Further, claim 60 of the '377 application is directed to the method for the identification and testing of active compounds for treatment of osteoporosis or Paget's disease.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments - Double Patenting

The rejection of claims 11 and 27 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59 and 60 of copending Application No. 10/622,377 is moot in view of Applicant's cancellation of the claims in the reply filed 9/11/2008.

With respect to the rejection of claims 9, 18, 21, 22 and 28 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 59 and 60 of copending Application No. 10/622,377, Applicant's arguments filed 9/11/2008 have been fully considered but they are not persuasive. Applicant requests that the issue be held in abeyance. Therefore, the rejection is maintained for reasons of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 18, 21, 22 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Maher et al (US Patent No. 6,686,193 B2, cited in a prior action; see the entire reference). This is a new rejection.

Claims 9 and 28 are drawn to a method comprising the following method steps: (a) providing a test cell comprising one or more ClC-7 chloride channels expressed in osteoclasts and of the ClC family; (ii) subjecting the test cell to the action of the chemical compound; and

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(c) measuring the ability of the chemical compound to block ClC7 chloride channel. Claim 18 is drawn to the step of screening compounds in a test cell so as to select compounds having the ability to block chloride channel ClC-7 expressed in osteoclasts and of the ClC family. Claim 21 requires compounds to be selected to block ClC-7 but not having the ability to block a chloride channel selected from the group consisting of chloride channels ClC-1, ClC-2, ClC-4, ClC-5, ClC-Ka and ClC-Kb. Claim 22 requires screening to select compounds that specifically block ClC-7. The phrase “expressed in osteoclasts” does not limit the cell type used in the claimed method. The claims encompass the use of any cell. Further, the phrase “wherein the screening method identified compounds having potential activity in treating osteoporosis, osteolytic cancer invasion, or Paget’s disease of bone” does not limit the method steps practiced. The positive action method steps would necessarily identify such compounds.

Regarding claims 9, 18 and 28, Maher et al teach a method for screening chemical compounds for activity in blocking ClC-7, a voltage gated chloride channel, comprising the steps of (i) providing a cell transfected with a nucleic acid encoding the ClC-7 channel and a control cell that is un-transfected, (ii) subjecting the cells to a chemical compound, and (iii) measuring the ability of the compound to block the voltage gated chloride channel (e.g., columns 46-48, (c) d) Assay of voltage-dependent chloride channels; Table 3).

Regarding claim 21, Maher et al teach the further testing to establish the specificity of the candidate modulator by testing cell lines containing related ion channel family members (e.g., paragraph bridging columns 58-59). Maher et al teach that voltage gated chloride channels related to ClC-7 include ClC-1, ClC-2, ClC-4, ClC-5, ClC-Ka, and ClC-Kb (e.g., Table 3).

Regarding claim 22, Maher et al teach the further screening of the compounds so as to select compounds with specificity for the particular channel being studied (e.g., columns 58-59, d) Selectivity of Candidate Modulators).

Accordingly, Maher et al teach each of the claimed method steps, which would necessarily result in the identification of channel blockers that have the potential ability to treat osteoporosis, osteolytic cancer invasion, or Paget's disease of the bone.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

/JD/

/Celine X Qian /
Primary Examiner, Art Unit 1636